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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' BRIEF REGARDING FDA WARNING LETTER

(Assigned to the Honorable David G. Campbell)

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This Brief addresses this Court's request for additional information concerning the contents and dates of certain of the complaints identified in the Warning Letter. Contrary to Plaintiff's counsel's argument, the complaints identified in the Warning Letter Topic 3.c are not "almost exactly the scenario of what Ms. Booker experienced." (Tr. Trans. at 905:4-5.) The one complaint from Topic 3.c that concerns a filter fracture was timely submitted as an MDR months before Plaintiff's filter retrieval procedures. Additionally, whether Bard timely reported as MDRs the other complaints identified in Topic 3.c has no impact on this matter because neither Plaintiff's treating physicians involved in her retrieval procedures, nor Plaintiff herself, testified that they reviewed or relied on information on the MAUDE database. Therefore, any failure to timely report these complaints could not have any causative impact on Plaintiff's case.

DISCUSSION

Warning Letter Topic 3.c concerns eight internal Bard complaints that FDA asserted "do not document sufficient information to allow for adequate complaint investigation and disposition, including MDR determination." (*See* July 13, 2015 FDA Warning Letter at p.5.)[1] Prior to receipt of the Warning Letter, Bard submitted MDRs for two of these complaints. (*See* Excerpt from Bard's Aug. 3, 2015 Warning Letter Response to FDA, at Bates page BPV-17-01-00200408.) The following is a summary of these complaints, all of which were received by Bard from a single physician in 2013:

- 507112 -- Bard's complaint description states, "[i]t was reported that during a vena cava filter retrieval approximately seven months post-implantation, the filter could not be retrieved. There was no reported patient injury." The complaint concerns a G2 filter. Bard submitted its initial MDR for this complaint in July 2015, after receipt of the Warning Letter.

[1] The complaints identified in Topic 3.b concern eight MDR reports that Bard submitted as "malfunctions" instead of "serious injury" or, for one complaint, death. But all of these complaints were originally timely reported to FDA. The four complaints in Topic 7 all concern alleged deployment issues with the Denali Filter. Finally, Topic 3.a concerns complaint handling for complaints involving a device or device components provided by suppliers. The only Bard IVC filter for which Bard uses third-party manufacturers for component parts is the Denali Filter. Bard's previous generation IVC filters, including the G2, were manufactured exclusively by Bard.

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- 507109 -- Bard's complaint description states, "[i]t was reported that during the scheduled retrieval of a vena cava filter approximately two months after implantation, the filter could not be retrieved. There was no reported patient injury." Bard was unable to obtain information concerning the model of filter. Bard submitted its initial MDR for this complaint in July 2015.

- 507115 -- Bard's complaint description states, "[i]t was reported that during the scheduled filter retrieval approximately two months after filter implantation, the tilted filter could not be retrieved. The filter remains implanted. There was no reported patient injury." Bard was unable to obtain information concerning the model of filter. Bard submitted its initial MDR for this complaint in July 2015.

- 507252 -- Bard's complaint description states, "[i]t was reported that during the scheduled retrieval of a vena cava filter approximately five months post implantation, the tilted filter was noted to be tilted in the IVC. The filter was unable to be retrieved and remains implanted. There was no reported patient injury." Bard was unable to obtain information concerning the model of filter. Bard submitted its initial MDR for this complaint in 2013 (MDR 2020394-2013-00394), before the Warning Letter, and before Plaintiff's retrieval procedures.

- 507280 -- Bard's complaint description states, "[i]t was reported that during the scheduled vena cava filter retrieval approximately two months after implantation, the tilted filter could not be retrieved. There was no reported patient injury." Bard was unable to obtain information concerning the model of filter. Bard submitted its initial MDR for this complaint in July 2015.

- 507302 -- Bard's complaint description states, "[i]t was reported that during the scheduled vena cava filter retrieval approximately four months after implantation, the filter could not be retrieved. There was no known impact or consequence to the patient." Bard was unable to obtain information concerning the model of filter. Bard submitted its initial MDR for this complaint in July 2015.

- 507311 -- Bard's complaint description states, "[i]t was reported that approximately one month post vena cava filter deployment, the tilted filter could not be retrieved. There was no reported patient injury." Bard was unable to obtain information concerning the model of filter. Bard submitted its initial MDR for this complaint in July 2015.

- 507325 -- Bard's complaint description states, "[i]t was reported that during the scheduled retrieval of a vena cava filter, imaging demonstrated a detached limb in the IVC in the vicinity of the filter. The filter and the detached limb were unable to be retrieved and they remain implanted. There was no reported patient injury." Bard was unable to obtain information concerning the model of filter at issue. Bard submitted its initial MDR for this complaint in 2013 (MDR 2020394-2013-00350), before the

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Warning Letter, and before Plaintiff's retrieval procedures.

The above-referenced complaints are not comparable to Plaintiff's case. Unlike Plaintiff's case -- where her physician was able to percutaneously retrieve her G2 filter -- these eight patients were unable to have their filters retrieved. None of the eight patients experienced any alleged injury. And, for the one patient who experienced a filter fracture (involving an unknown filter model), Bard timely reported the complaint to FDA in 2013, months before Plaintiff's retrieval procedures.

Additionally, contrary to Plaintiff's counsel's assertion, FDA did not criticize Bard for failure to warn doctors, do "appropriate follow-up," or perform "root cause analysis" of these eight complaints. (Tr. Trans. at 908:2-4.) Instead, FDA simply stated that Bard's complaint files do not document sufficient information for adequate investigation and MDR determination. Finally, that Bard did not report six of these complaints to FDA until after receipt of the Warning Letter does not impact Plaintiff's claims for failure to warn (including any continuing duty to warn), as Plaintiff's counsel alleges. (*See* Tr. Trans. 907:22-24; 912:11-13.) Neither the physicians involved in Plaintiff's retrieval procedures, nor Plaintiff herself, testified that they rely on the MAUDE database. Thus, any failure by Bard to timely report these complaints could not have had any causative impact on Plaintiff's claims or injuries.[2]

CONCLUSION

For these reasons, Defendants respectfully request that this Court exclude the FDA Warning Letter from evidence.

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[2] Plaintiff's implanting physician, Dr. D'Ayala, testified his review of the MAUDE database impacted his decision to stop using Bard's IVC filters. (D'Ayala Dep., March 21, 2017, at 31:19 to 32:1.) But Dr. D'Ayala never treated Plaintiff after implanting the G2 filter in 2007, (*see id.* 24:3-5), and Bard's alleged failure to timely report complications in 2013 could not possibly have impacted Dr. D'Ayala's decision to use a G2 Filter in 2007.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of March, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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